Section 3 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K131762

1. Date of Submission: 6/6/2014

2. Sponsor Identification

Guangdong Biolight Meditech Co., Ltd.
No.2 Innovation First Road, Technical Innovation Coast,
Hi-tech Zone, Zhuhai, P.R. China

Establishment Registration Number: 3007305624

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3. Submission Correspondent

Ms. Diana Hong & Mr. Lee Fu
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120, China
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4. Proposed Device Identification

Proposed Device Name: Handheld Monitor
Proposed Device Model: M800
Proposed Device Common Name: Patient Monitor

Regulatory Information:
Classification Name: Monitor,Physiological,Patient(Without Arrhythmia Detection Or Alarms);
Classification: II;
Product Code: MWI;
Regulation Number: 21 CFR 870.2300;
Cardiovascular;
Subsequent Product Code: DRT, DQA

Intended Use Statement:

M800 handheld monitor is intended for continuously monitoring or spot checking of SpO_2, PR, ECG and HR of adult, pediatric and neonatal patients in hospital, hospital type facilities as well as in the home care environment.

5. Predicate Device Identification

510(k) Number: K100046
Product Name: M Series Patient Monitor
Manufacturer: Guangdong Biolight Meditech Co., Ltd.

6. Device Description

The proposed device, M800 is a handheld patient monitor used to monitor for continuously monitoring and spot checking of SpO_2, PR, ECG and HR of adult, pediatric and neonatal patients.

The proposed device includes three display modes for monitoring results, data review function, and audio and visual alarming function.

It consists of four functional modules, which are power supply module, parameter measurement module, main control and human-device interface.

7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance, 1998; Amendment 1, 1991; Amendment 2, 1995.
- IEC 60601-1-2:2007, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.
- ISO 9919:2005, Medical electrical equipment - Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use.
- IEC 60601-2-27: 2005, Medical electrical equipment - Part 2-27: Particular requirements for the safety including essential performance, of electrocardiographic monitoring equipment.
- AAMI / ANSI EC13:2002/(R)2007, Cardiac monitors, heart rate meters, and alarms.

8. Guidance

The following FDA guidance documents were followed when the submission data were prepared:

- Pulse Oximeters - Premarket Notification Submissions [510(k)s] Guidance for Industry and Food and Drug Administration Staff;
- Guidance for Industry Cardiac Monitor Guidance (including Cardiotachometer and Rate Alarm).

9. Substantially Equivalent (SE) Conclusion

The following table compares the DEVICE to the predicate device with respect to intended use, technological characteristics and principles of operation, etc.

Table 3-1 Comparison of Technology Characteristics

Item	Proposed Device(s)	Predicate Device(s)
Product Code	MWI	Similar
Regulation Number	21 CFR 870.2300	Similar
Class	Class II	Same
Intended Use	M800 handheld monitor is intended for continuously monitoring or spot checking of SpO_2, PR, ECG and HR of adult, pediatric and neonatal patients in hospital, hospital type facilities as well as in the home care environment.	Similar
Display	TFT	Same
Alarm	Visual and audio alarming	Same
SpO2 Range	BLT Module: 0~100% Necllor Module: 0% to 100%	Same
SpO2 Accuracy	BLT Module: 70% to 100%: ±2% 0% to 69%: unspecified Necllor Module: 70% to 100%: ±2%（adult/pediatric） 70% to 100%: ±3%（neonate） 70% to 100%: ±2%（low perfusion） 0% to 69%, unspecified	Same
PR Range	BLT Module: 25 bpm to 255 bpm Necllor Module: 20 bpm to 300 bpm	Same
PR Accuracy	BLT Module: ±1% or ±1 bpm, whichever is the greater Necllor Module: 20bpm~250bpm: ± 3 bpm 251bpm~300bpm: unspecified	Same
ECG Lead	3 lead: I, II, III	Same
ECG Gain	2.5mm/mV(×0.25), 5mm/mV(×0.5), 10mm/mV(×1)	Same
Sweep Speed	12.5mm/s, 25mm/s	Same
HR Rang	10 bpm ~300 bpm	Same
HR Accuracy	±1% or ±1 bpm, whichever is the greater	Same

Electrical Safety	Comply with IEC 60601-1	Same
EMC	Comply with IEC 60601-1-2	Same
Patient-contact Material	ECG Cable: TPU	Same

The proposed device, Handheld Monitor M800, is determined to be Substantially Equivalent (SE) to the predicate device, M Series Patient Monitor (K100046), in respect of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 6, 2014

Guangdong Biolight Meditech Co., Ltd.
c/o Ms. Diana Hong
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120 CHINA

Re: K131762
Trade/Device Name: Handheld Monitor (M800)
Regulation Number: 21 CFR 870.2300
Regulation Name: Patient Monitor
Regulatory Class: Class II
Product Code: MWI, DRT, DQA
Dated: April 29, 2014
Received: May 1, 2014

Dear Ms. Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

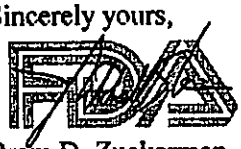
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 2 Indications for Use

510(k) Number:
Device Name: Handheld Monitor M800

Indications for Use:

M800 handheld monitor is intended for continuously monitoring or spot checking of SpO_2, PR, ECG and HR of adult, pediatric and neonatal patients in hospital, hospital type facilities as well as in the home care environment.

☒PRESCRIPTION USE
(Part 21 CFR 801 Subpart D)

OR

☐OVER-THE-COUNTER USE
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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